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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/169,196 10/09/98 RIDER T 01997/227002

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EXAMINER

CHIN, C

ART UNIT

PAPER NUMBER

1641

12

DATE MAILED:

08/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/169,196

Applicant(s)

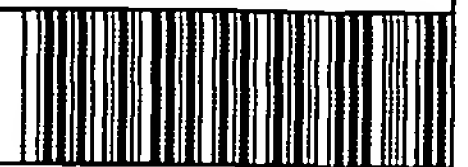
Rider

Examiner

Chris Chin

Group Art Unit

1641



☒ Responsive to communication(s) filed on Jun 13, 1900

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-22 is/are pending in the application.

Of the above, claim(s) 18-22 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-17 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-22 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5 & 8

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group I - claims 1-17 in Paper No. 11 is acknowledged.

Drawings

2. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 U.S.C. § 112

3. Claims 1-3, 5-11, and 13-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of B-cells, does not reasonably provide enablement for the use of cells in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification is not enabling for the use of any cells in the device of claims 1 and 9. Claims 1 and 9 broadly recite the use of any cell in the claimed device. However, the specification only teaches the use of B-cells in the claimed device, see page 1 of the instant specification, or fibroblasts with expressed chimeric surface antibodies, see page 4 of the instant specification. B-

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cells and fibroblasts with expressed chimeric surface antibodies are the only cells taught by the specification that are capable of expressing antibodies on their surface which can bind to a corresponding antigen and produce increased levels of calcium in response to antigen binding to the antibodies. Claims 1 and 9 broadly encompass the use of cells, such as epithelial or somatic cells, which do not express antibodies on their surface nor produce elevated levels of calcium in response to an antigen-antibody binding event.

The specification is not enabling for the use of fibroblasts without expressed chimeric surface antibodies as recited in claims 5 and 13. Page 4 of the instant specification teaches that “fibroblasts do not contain the signal transduction machinery necessary to transfer a signal from the cytoplasmic portion of a surface antibody to calcium stores in the cell”. The specification goes on to teach that “a chimeric surface antibody can be expressed in the fibroblast” to overcome this problem with the fibroblasts. The claimed device relies on signal transduction between the cell surface and the calcium stores in the fibroblast to permit detection of analyte that may contact the fibroblasts. As taught by the specification, the lack of expressed chimeric surface antibody on the fibroblasts, as recited in claims 5 and 13, would yield an inoperative device.

4. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1 and 9 are vague and indefinite. The claims do not set forth how each of the components are structurally related to each other.

Claims 2 and 10 are vague as it is not clear as to how the detector can be affixed to a liquid medium.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-4, 9-12, and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,087,114.

Although the conflicting claims are not identical, they are not patentably distinct from each other because patent '114 claims a device for detecting an antigen comprising essentially the same components as the instantly claimed device. The device of patent '114 differs from the instantly claimed device in reciting the use of specific cells, (i.e. B cells). However, it would have been

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obvious to one of ordinary skill in the art that the recitation of "cell" in the instant claims broadly encompasses the B cells recited in the device of patent '114.


Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 9:30 am to 7:00 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

cchin/cc
August 18, 2000


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641